DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2015

DJO, LLC
Gina Flores
Regulatory Specialist
1430 Decision Street
Vista, CA 92081

Re: K143551
Trade/Device Name: Compex Wireless USA
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: March 25, 2015
Received: March 27, 2015

Dear Ms. Flores:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological and
Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143551

Device Name
Compex Wireless USA

Indications for Use *(Describe)*
The Compex Wireless USA is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.

The Compex Wireless USA is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the Compex Wireless USA stimulation programs are designed for injured or disease afflicted muscles. Its use on such muscles is contraindicated. The work imposed on the muscles by the Compex Wireless USA programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Wireless USA electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

The Compex Wireless USA may therefore be considered a technique of muscle training.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5. 510(k) Summary

This 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92. The assigned 510(k) number is K143551.

Submitted by:	DJO, LLC 1430 Decision Street Vista, CA 92081
Contact Person:	Gina Flores Regulatory Specialist 760-734-3161
Date Summary Prepared:	April 16, 2015
Trade Name:	Compex® Wireless USA
Classification Name:	Powered muscle stimulator (21 CFR 890.5850)
Product Code:	NGX, Powered muscle stimulator, for muscle conditioning.
Regulatory Class:	Class II
Predicate Device:	Compex Sport Elite (k083140)

Device Description:

The Compex Wireless USA is a neuromuscular electrical stimulation (NMES) device, which stimulates nerve fibers by means of electrical impulses transmitted by electrodes. The electrical pulses generated by the Compex Wireless USA stimulate motor nerves to stimulate a muscular response. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, and total session duration), different types of muscle work can be imposed on the stimulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training.

The device system is made up of a remote control, 4 stimulation modules, and electrodes, which are stored and shipped within the docking station which is used to recharge the remote and the modules. The docking station is powered by an AC-DC adapter.

The remote control is the interface between the stimulation modules and the user. It sends and receives information to and from the modules via a wireless network. The remote control allows the user to navigate through the user interface (UI), select stimulation program or objectives, set desired options and control the four (4) module intensities independently. The remote control is powered by a rechargeable battery.

The Compex Wireless USA stimulation module set is composed of 4 independent stimulation modules that are controlled via the remote control by a wireless connection. Each module is composed of two "pods" (1 battery "pod" and one stimulation "pod") linked by an electrical connection (cable). Two proprietary Compex standard snap gel electrodes are also needed to connect each "pod" to the body. The modules are powered by a Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 450 [mAh] battery.

The wireless protocol of the Compex Wireless USA Device is a proprietary design of a Radio-Frequency protocol operating the 2.4 GHz ISM band. It is used to 1) Send particular information from remote control to stimulation modules (stimulation settings) 2) Send particular information from stimulation modules to remote control, like current stimulation level and stimulation module subsystem status, 3) Transfer binary data to stimulation modules, and 4) Allow synchronization from stimulation modules to remote control clocks.

Intended Use:

Indications for Use:
The Compex Wireless USA is an Over-The-Counter device intended to stimulate healthy muscles in order to improve or facilitate muscle performance. It is to be used by adults only.
The Compex Wireless USA is not intended for adjunctive therapy in the treatment of medical diseases and conditions of any kind. None of the Compex Wireless USA stimulation programs are designed for injured or disease afflicted muscles. Its use on such muscles is contraindicated. The work imposed on the muscles by the Compex Wireless USA programs is definitely not suitable for rehabilitation and physiotherapy. The Compex Wireless USA electrical impulses allow the triggering of action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles. The Compex Wireless USA may therefore be considered a technique of muscle training.

Programs:
Muscle Stimulation Training Programs: The Compex Wireless USA provides four muscle stimulation training programs: Endurance, Resistance, Strength, and Explosive Strength. They correspond to the type of muscle performance the athlete wishes to improve or maintain. Each of the four training programs offers five different working levels that enable the amount of work to be gradually increased.

Specialized Muscle Training Programs: The Compex Wireless USA also offers five special muscle training programs: Potentiation, Training Recovery, Competition Recovery, Muscle Relaxation, and Pre-Warmup. Their objective is to prepare muscles

for explosive motions or to facilitate recovery after active muscle training and competition.

Comparison to the Predicate Device:

The indications for use for the Compex Wireless USA are identical to those of the predicate device, the Compex Sport Elite. In addition, the 9 NMES programs are identical in both devices.

The technological characteristics of the two devices are very similar, but there are a few minor differences. The following tables summarize the similarities and differences between the technological characteristics of the two devices.

Basic Device Characteristics – Comparison with Predicate Device

Characteristic	New Device	Predicate Device	Similar/ Different
510(k) Number	K143551	K083140	
Device Name, Model	Compex® Wireless USA	Compex Sport Plus (currently marketed as Compex Sport Elite)	Similar
Manufacturer	DJO LLC	DJO LLC 510(k) sponsor: Chattanooga Group	Similar
Connection of device to electrodes	Stimulation Module is directly connected to the custom Compex female SNAP assembled in the electrode. User Interface (LCD and buttons) is physically separated (Remote Control) and communicates wirelessly with up to four (4) Stimulation Modules. Stimulation safety remains fully managed by Stimulation Module electronic circuit itself.	With 6-pole cables including female custom SNAP plugged on the custom Compex female SNAP assembled in the electrode. Entire electronic circuit for four (4) Stimulation Channels and User Interface is combined into same casing, connected to the electrodes with 6-pole cables.	Different
Power Source(s)	Remote: : Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 1500[mAh Stimulation Modules: Lithium Polymer (LiPo) rechargeable 3.7[V] / ≥ 450[mAh]	Rechargeable Ni-Mh Battery 4.6V (4 cells AA=R6)	Different
- Method of line current isolation	N/A (battery operated device)	N/A (battery operated device)	Similar

- Patient Leakage Current	N/A (battery operated device)	N/A (battery operated device)	Similar
• Normal condition	N/A (battery operated device)	N/A (battery operated device)	Similar
• Single fault condition	N/A (battery operated device)	N/A (battery operated device)	Similar
Number of Output Modes	One (NMES)	One (NMES)	Similar
Number of Output Channels	Four	Four	Similar
- Synchronous or Alternating?	Synchronous, but never 2 channels activated at the same time	Synchronous, but never 2 channels activated at the same time	Similar
- Method of Channel Isolation	Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state.	Each channel is the middle of a H-Bridge. Except when it is activated, each channel is always in high impedance state.	Similar
Regulated Current or Regulated Voltage?	Regulated current (all channels)	Regulated current (all channels)	Similar
Software/Firmware/ Microprocessor Control?	Yes	Yes	Similar
Automatic Overload Trip?	Yes	Yes	Similar
Automatic No-Load Trip?	Yes	Yes	Similar
Automatic Shut Off?	"On/Off" switch	"On/Off" switch	Similar
Patient Override Control?	Yes	Yes	Similar
Indicator Display - On/Off Status?	Yes	Yes	Similar
- Low Battery?	Yes	Yes	Similar
- Voltage/Current Level?	Yes, unit = [Energy]	Yes, unit = [Energy]	Similar
Timer Range (minutes)	Maximum = 48 minutes; Screen shows remaining time in minutes and displays image showing time remaining	Maximum = 55 minute Screen shows remaining time in minutes and seconds and displays countdown timer	Different
Compliance with 21 CFR 898?	Yes	Yes	Similar
Charging System	AC/DC 5[v] 3.5[A]; Distributed through docking station to remote	AC/DC 9[v] 0.4[A] Distributed directly to the device	Different

	and 4 modules		
Weight	- Remote: 110 [g] - Stimulation Module:2x60 [g] - Docking Station 800 [g]	300 [g]	Different
Dimensions [W x H x D]	- Remote 9x4.5x0.7[cm] - Stimulation Module: 6.5x2 [cm] - Docking Station: 25x25x2 [cm]	99 x 142 x 36 [mm] 3.9 x 5.6 x 1.4 [in]	Different

Output Specifications – Comparison with Predicate Device

Characteristic	New Device	Predicate Device	Similar/ Different
Waveform	Symmetrical Biphasic	Symmetrical Biphasic	Similar
Shape	Rectangular	Rectangular	Similar
Maximum Output Voltage (± 10%)	60 V @ 500 Ω 180V @ 2 kΩ 180 V @ 10 kΩ	60 V @ 500 Ω 165 V @ 2 kΩ 165 V @ 10 kΩ	Different
Maximum Output Current (± 10%)	120 mA @ 500 Ω 90 mA @ 2 kΩ 18 mA @ 10 kΩ	120 mA @ 500 Ω 82 mA @ 2 kΩ 16 mA @ 10 kΩ	Different
Pulse Width	300 to 400 [µs] (microseconds)	200 to 400 [µs] (microseconds)	Different
Frequency	1 to 120 Hz	1 to 120 Hz	Similar
For multiphasic waveforms only: - Symmetrical phases? - Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	Symmetrical, 300 - 400 µs	Symmetrical, 200 - 400 µs	Different
Net Charge [µC/pulse]	0 [µC] @ 500Ω Excitation pulse fully compensated	0 [µC] @ 500Ω Excitation pulse fully compensated	Similar
Maximum Phase Charge [µC]	48 [µC] @ 500Ω	48 [µC] @ 500Ω	Similar
Maximum Current (RMS) Density [mA/cm^2]	1.49 [mA/cm^2] @ 500Ω	1.49 [mA/cm^2] @ 500Ω	Similar
Maximum Power Density [mW/cm^2]	27.6 [mW/cm^2] @500Ω	27.6 [mW/cm^2] @500Ω	Similar

Although there are minor differences in the maximum output voltage and current, the physical dimensions, the timer range, the batteries used as a power source, and the battery charging specifications, the most significant difference between the two devices is the connection of the device to the electrodes. The Compex Wireless USA uses wireless technology, whereas the predicate device uses 6-pole cables. This type of wireless technology is used in other OTC devices, such as the WiTouch TENS device (k1120500). None of these differences, including the use of wireless technology, raise any new issues of safety or effectiveness.

Performance Testing:

Electrical Safety and Electromagnetic Compatibility: The Compex Wireless USA was tested and found to comply with recognized standards for electrical safety and electromagnetic compatibility.

FCC Radio Frequency Testing: The Compex Wireless USA was tested to FCC requirements and found to comply with the requirements of 47 CFR 15.249.

Software Verification: The device's software was verified in accordance with the requirements of FDA's guidance document: General Principles of Software Validation, January 11, 2002. The software testing demonstrated that the software meets its design requirements.

Usability/Human Factors Testing: Usability/Human Factors testing was performed, which demonstrated that the established requirements for usability were met, and the device's design is appropriate for the intended users and use environment. The result of this study substantiates the acceptability of the use-related risks identified during the risk assessment activities.

Wireless Coexistence Testing: The performance of Compex Wireless USA was evaluated in an environment with other Compex Wireless USA device and with other types of 2.4 GHz wireless devices (Bluetooth and Wi-Fi). The device met all specified requirements.

Standards:

The Compex Wireless USA conforms to the following standards.

Designation	Name	FDA Recognition
AAMI/ANSI ES 60601-1:2005(R)2012 and C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text). Compex Wireless USA device	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance	19-5
IEC 60950-1:2005 (2nd Ed.): Docking Station Only	Information Technology Equipment – Safety – Part 1: General requirements	N/A

IEC 60601-1-2 Ed. 3:2007-03: Compex Wireless USA device	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	19-1
EN 55022:2010/AC:2011 Docking Station only	Information Technology Equipment – Radio Disturbance Characteristics – Limits and Methods of Measurement	N/A
EN 55024:2010 Docking Station only	Information Technology Equipment – Immunity Characteristics – Limits and Methods of Measurement	N/A
EN 61000-3-2:2006 +A1:2009 +A2:2009 Docking Station only	Electromagnetic Compatibility (EMC) – Part 3.2: Limits – Limits for Harmonic Current Emissions (Equipment Input Current Less Than or Equal To 16 A per Phase).	N/A
EN 61000-3-3:2013 Docking Station only	Electromagnetic Compatibility (EMC) – Part 3.3: Limits – Limitation of Voltage Changes, Voltage Fluctuations and Flicker in Public Low-Voltage Supply Systems, for Equipment with Rated Current Less Than or Equal To 16 A per Phase and Not Subject to Conditional Connection	N/A
IEC 60601-1-6 Ed. 3.0: 2010-01	Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability	5-85
IEC 60601-1-11 Ed. 1.0: 2010-04	Medical Electrical Equipment – Part 1-11: General Requirements – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment	19-6
IEC 60601-2-10 Ed. 2.0 2012-06	Medical Electrical Equipment – Part 2-10: Particular Requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators	17-11
IEC 62366:2007	Medical Devices – Application of Usability Engineering to Medical Devices	N/A
AAMI/ANSI HE75:2009	Human Factors Engineering – Design of Medical Devices	5-57
ISO 14971:2007	Medical Devices – Application of Risk Management to Medical Devices	5-40
IEC 62304 First Ed. 2006-05	Medical Device Software – Software Life Cycle Processes	13-8

Conclusion:

Based on the performance testing and the similarities of the indications for use and the technological characteristics, it can be concluded that the Compex Wireless USA is as safe and effective as, and substantially equivalent to, the predicate device.